

PSJ3
Exhibit 235

Message

From: Ducca, Anita [aducca@hdmanet.org]
Sent: 9/13/2007 7:26:35 PM
To: Ducca, Anita [aducca@hdmanet.org]
Subject: HDMA Update and RAC Conference Call Cancellation Notice
Attachments: CMS Qs and As - Tamper Resistant Pads 08-07.pdf; CMS Letter Tamper Resistant Pads 08-07.pdf

Dear RAC Members,

This is to give you an update on current issues.

1. The RAC meeting scheduled for Thursday, Sept. 20, has been **CANCELLED** due to a conflicting meeting that the DEA has scheduled on that date (on Methadone). I will be attending the DEA meeting. It is my understanding that DEA intends to invite some of our members, as well.

2. As you know, DEA issues were on the agenda for the GPPC meeting that took place over the last 2 days. The following summarizes the discussion/decisions they reached:

- *Suspicious Orders:* GPPC requested that HDMA staff draw up and describe a multi-pronged strategy with possible approaches for dealing with DEA on the Suspicious Orders issue that is to be given to the Executive Committee for review and direction next week. The strategy with potential options would include such elements as: additional meetings with the DEA, potentially developing a set of "best practices," meetings on the Hill, etc.
- *Methadone:* GPPC felt that HDMA should not speak at the DEA meeting on Sept. 20th. We should, instead, attend to learn more about it. The general reaction was that this was a prescribing problem, not one of distribution. If HDMA were to become more involved, more information was needed before speaking at such a meeting.
- *In-Transit Losses:* Since most of the allotted time had been taken up with the two items above, we only had a few minutes to discuss In-Transit Losses, so there wasn't much feedback or a decision on whether or how to go forward. However, we'll continue to look at the idea of best business practices.

3. I attended the DEA Pharmaceutical conference on Tuesday, Sept. 11. Since many of you were also at the meeting, and since DEA will be posting the slides on their web site, I'll just briefly recap key agenda items regarding issues we would be most concerned about.

- *In-Transit Losses:* There wasn't much new information, mostly the presentations focused on the problems with a few solutions, for example, by including tracking devices on the trucks. Kevin Nicholson of NACDS gave a presentation pharmacy practices to prevent thefts, but did not cover much having to do with In-Transit ones. A representative of a FedEx division discussed a few of the precautionary measures they take. DEA did say that they're considering a regulation and that one element they may look at is a requirement for tracking devices (on the trucks). They also noted that they eventually found the truck with the 16 million dosage units of hydrocodone that had been stolen a few months ago. Most of the product was still on the truck.
- *On Suspicious Orders,* Mike Mapes of DEA gave a brief overview, stressing the idea that there was both a responsibility to report suspicious orders, but also a responsibility to take steps to guard against diversion. Mike noted that in the DEA's mind, this means that if an order is suspicious, it shouldn't be shipped. Chris Zimmerman of ABC also gave a description of ABC's program to fulfill these responsibilities.
- *On Methadone,* DEA gave an extensive overview of the prescribing issues with descriptions of the mortality rates, states where this is occurring, etc.. They did not discuss possible methods to prevent prescribing problems.

4. We thought you might be interested in a communication for Pharmacists from the Centers for Medicare and Medicaid Services (CMS) on Tamper Resistant Prescription Pads. This requirement goes into effect on October 1. They have issued the following statement:

On August 17, 2007, CMS issued a State Medicaid Director Letter offering guidance to State Medicaid agencies regarding use of tamper-resistant prescription pads. In follow-up to this letter, CMS received a number of questions from States, pharmacists and other providers about the details of the implementation. CMS has developed the attached Frequently Asked Questions document, with information about retroactive eligibility, emergency fills, drug orders and more, to assist partners as they implement this requirement for October 1, 2007.

Copies of the State Medicaid Director Letter and the FAQs are attached.

5. You will be hearing from us shortly on iPLEDGE. As I mentioned in a previous e-mail, I'll be scheduling a conference call on the compliance questions that Covance has raised but first will be updating the iPLEDGE Task Force roster.

Again, as noted above, we will **not** have a conference call on Thursday, Sept. 20.

If you have any questions, please feel free to contact me.

Anita

Anita T. Ducca
Senior Director, Regulatory Affairs and Healthcare Policy
Healthcare Distribution Management Association
(703) 885-0240
Fax: (703) 935-3200
www.HealthcareDistribution.org